

Exhibit 28

PIC/S 2016 Annual Seminar - Inspectorates of the Future

Hosted by MHRA, Museum of Science and Industry, Manchester, UK (www.mosi.org.uk)

6 – 8 July 2016.

Wednesday 6th July 'Inspection trends and future developments'

Time	Topic
09.00	Welcome to Seminar – Head MHRA Inspectorate (M Birse) Opening addresses – Chief Executive MHRA & PIC/S Chairman (I Hudson / P Hargreaves) Introduction to Agenda – Head MHRA Inspectorate (M Birse)
09.30	Inspections trends & GMP deficiencies – (P Gustafson) <ul style="list-style-type: none"> Pre-seminar questionnaire – follow up from South Africa on trends Deficiency classification – TGA (WG on harmonization on classification).
10.30	Break
11.00	Data Integrity - Issues identified and inspection techniques MHRA & TGA (D Churchward) <ul style="list-style-type: none"> Note link back to anything in 09.30 slot
11.45	Industry developments – Speaker from the GPMLF Global Pharmaceutical Manufacturers Leadership Forum or Strathclyde University Grant people or Government speaker on pharmaceutical business trend (HPRA) - MHRA to arrange
12.30	Lunch
13.30	Workshop 1 – Inspection trends and inspection strategies for the future (link to 0930 speakers +3-4 MHRA to support) P Gustafson + MHRA support <ul style="list-style-type: none"> Review and comparison of trends globally – output: new PIC/S article Use GPMLF GPS document to map gaps in inspector knowledge – output: for PIA to use Workshop 2 – Data Integrity (link to 0930 speakers +3-4 MHRA to support) (TGA/FDA/MHRA) - MHRA to arrange once delegates known <ul style="list-style-type: none"> Workshop showing practical examples of how to inspect Gather additional techniques from group – output: for collation by drafting group
15.00	Break
15.30	Workshop 1 – Inspection trends and inspection strategies for the future Workshop 2 – Data Integrity
17.00	Close

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Thursday 7th July 'Inspectorates of the Future'

Time	Topic
09.00	Scene setter for day - MHRA to arrange
09.10	Working together – TGA (H Rothenfluh) + EMA (P Krauze) or WHO <ul style="list-style-type: none"> PIC/S, ICMRA etc Reliance frameworks – maximising resources Information sharing – what needed and when Practicalities & legalities of Office/Desktop Based Inspections
09.35	Risk based inspections – (J Morenas / Ian Jackson) <ul style="list-style-type: none"> Review of PIC/S approach Drivers and intel needed Whistle-blowers Pre-seminar questionnaire – MHRA to establish with session lead
10.30	Break
11.00	Compliance Management – FDA (S Laska/ E Morrison) <ul style="list-style-type: none"> Increase patient safety and security of supply What is done beyond inspections to drive compliance Pre-seminar questionnaire - MHRA to establish with session lead
11.45	Shortages and complex supply chain – Industry speaker (supply chain shortages group) – MHRA to arrange <ul style="list-style-type: none"> Drivers for shortages / assessors view Increasing complexity / industry view
12.30	Lunch
13.30	Workshop 3 – Shortages EMA (P Krauze/Brendan Cuddy) + MHRA support <ul style="list-style-type: none"> Presentation on practical examples <ul style="list-style-type: none"> Inspectors 'role' in reducing shortages / inspectors view Greater understanding of work done in this area Develop guidance documents What can inspectors do – output: how PIC/S can promote work in this area Workshop 4 – Compliance Management FDA (with MHRA Support) <ul style="list-style-type: none"> Workshop discussing what inspectors/agencies do now Develop what more could be done and what PIC/S could do Whistle-blowers, how handled Gather from group – output: proposals for PIC/S to develop
15.00	Break
15.30	Workshop 3 – Shortages Workshop 4 – Compliance Management
17.00	Close

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Friday 8th July ‘A New Dawn’

Time	Topic
09.00	Introduction
09.00	PIA – Now & Next (Boon) <ul style="list-style-type: none"> Overview of PIA progress to all delegates What it will mean as an Inspector
09.30	Workshop feedback (x4) – 15 mins each Chair HPRA (A Hayes) + leaders of the workshops <ul style="list-style-type: none"> Recap of key messages Proposed output and next steps
10.30	Break
11.00	Foreign Travel Safety Awareness (Harry TGA/ MHRA) <ul style="list-style-type: none"> Risk Assessments – proactive and dynamic Security Alerts Cancelling inspections Working with inspectors in country
11.30	PIC/S Highlights and Vision to 2020 – Chair (P Hargreaves) <ul style="list-style-type: none"> Developed by EB members Highlights of WG and SC
12.00	2017 Seminar address – Chinese Taipei
12.15	Closing address & presentation of the PIC/S walking stick <ul style="list-style-type: none"> MHRA (M Birse) Chair PIC/S (P Hargreaves)
12.30	Lunch or depart

Workshop structure

- 2 workshops with approximately 70 people (7 x round table of 10)
- Each workshop 1.5 hours long and then swap
- 4 facilitators per workshop (MHRA to provide 2 Inspectors to support running of each)
- Technology used to capture feedback for all teams for instant review – iPads etc and voting technology